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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/462,993 | 04/17/00 | KIENY M | 017753-122 |

HM12/0329

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| WOITACH, J | |
| **ART UNIT** | **PAPER NUMBER** |
| 1632 | 10 |

**DATE MAILED:** 03/29/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

File

| Office Action Summary | Application No. 09/462,993 | Applicant(s) Kieny et al. |
|---|---|---|
| | Examiner Joseph Woitach | Group Art Unit 1632 |

☒ Responsive to communication(s) filed on *Feb 20, 2001*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) *21-40* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *21-40* are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

## DETAILED ACTION

Applicants amendment filed August 31, 2000, has been received and entered. The application is now in sequence compliance.

Applicants amendment filed February 20, 2001 has been received and entered. Claims 1-20 have been canceled. Claims 21-40 have been added. Claims 21-40 are pending and currently under examination.

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 21-37, drawn to a polynucleotide comprising at least one recombinant vector encoding an immunogenic polypeptide modified by inserting a membrane anchoring sequence.

Group 2, claim(s) 38, drawn to polypeptide comprising an immunogenic polypeptide modified by inserting a membrane anchoring sequence.

Group 3, claim(s) 39-40, drawn to a method for the treatment or prevention of cancer or a tumor in a subject comprising administering a polynucleotide comprising at least one recombinant vector encoding an immunogenic polypeptide modified by inserting a membrane anchoring sequence.

The inventions listed as Groups 1-3 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A) The invention has no special technical feature that defined the contribution over the prior art, or

B) Unity of invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

1) A product and a special process of manufacture of said product.

2) A product and a process of use of said product.

3) A product, a special process of manufacture of said product, and a process of use of said product.

4) A process and an apparatus specially designed to carry out said process.

5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant application, see MPEP § 1850.

Applicant's claims encompass multiple inventions and do not have a special technical feature which link the inventions one to the other, and lack unity of invention. Further, a immunogenic fusion protein containing a myc tag, a non-membrane protein, was operatively linked to the UBC6 sequence to produce a protein which was localized to the membrane of the cell in which it was expressed (Yang *et al.* JBC 272:1970-5). The reference does not state that the composition containing the fusion protein has antitumoral capabilities, however aberrant expression of myc has been implicated in cellular transformation during carcinogenesis.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: There are four separate species of an immunogenic polypeptide; 1. **L1**, 2. **L2**, 3. **E6** (set forth in SEQ ID NO: 1) and 4. **E7** (set forth in SEQ ID NO: 2).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument

that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: Claims 25-27 and 30 are drawn to the species of the immunogenic polypeptide derived from an early region of the papilloma virus. Claim 28 is drawn to the species of the immunogenic polypeptide derived from a late region of the papilloma virus.

The following claim(s) are generic: Claim 21-24, and 29-40 are generic to all species. Claims 25-27 and 30 are generic to both species of the immunogenic polypeptide derived from an early region of the papilloma virus as set forth in SEQ ID NO: 1 and set forth in SEQ ID NO: 2.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: When read in light of the specification, each of these sequences are derived from papillomavirus, however each is a different polynucleotide sequence which encodes a different polypeptide sequence. Though each species is derived from papillomavirus, each sequence is different and unique and would not anticipate the other and thus the search and review of one species would not be coextensive with another.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen M. Hauda, can be reached at (703)305-6608.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Kay Pickney whose telephone number is (703)306-3076.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER